

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Robert J. MEDOFF

Serial No.: 10/821,643

Group No.: 3775

Filed: April 9, 2004

Examiner: Swiger III, James L.

For: FRACTURE FIXATION SYSTEM INCLUDING BUTTRESS PIN AND POST  
WASHER

Attorney Docket No.: U 015145-3

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

**DECLARATION UNDER 37 CFR 1.132**

I, Robert J. Medoff, do hereby declare:

1. I am the inventor of the subject matter described and claimed in the above application.

I make this declaration in support of this application.

- 2 I consider myself to be skilled in the art of orthopedic medicine and apparatus by reason of my education and experience as shown on the curriculum vitae attached herewith as Exhibit I.

3. I am the patentee or co-patentee of the patents shown on the list attached herewith as Exhibit II.

4. In the aforesaid application 10/821,643, the Examiner has rejected the claims on the

combination of Medoff (US Patent No. 5,709,682) in view of Laboreau (US Patent No. 5,662,655).

5. I am the inventor of the aforesaid Medoff patent and am familiar with its content. I have studied the content of the Laboreau patent and am also familiar with its content.

6. The Examiner considers that Medoff discloses an implant comprising a single wire having a U-shaped bend (for example top view Fig. 2) defining a first region, with opposite legs extending from the U-shaped bend and are parallel, wherein said legs have distal ends (49) that are bent away (also, 5) and are capable of buttressing a surface of a bone (see Fig. 3). This portion of the legs comprise a second portion, aside from a first portion (approx, 41, which lies in the same plane as the U-shaped bend), wherein the second portion lies outside the first plane of the first portion. The legs are considered parallel to one another and the legs are of equal length in the view of Fig. 2. Medoff also discloses a pin in combination with a washer (6, Fig. 6) which can assist in holding the pin legs in relation to another, or alternatively, assist in holding or securing the pin to a bone (with an alternative pin 4). The implant of Medoff further disclose a bent portion (approx 41) that connects the two portions out of plane. The Examiner considers that Medoff discloses the claimed invention except for a region extending from the U-shaped bend which is a second region in proximity to the distal end, in which the spacing of the legs is different, or wherein the length of the legs in the distal region is unequal. Laboreau discloses a single piece implant device (see Fig. 2) that has two regions, one in proximity of the U-shaped bend, and a second region in proximity to the second region, and also has legs of different lengths (13/14) due to the various adjustments from the first region. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Medoff having at least a region extending from the U-shaped bend which is a second region in proximity to the distal end, in which the spacing of the legs is different, or wherein the length of the legs in the distal region is unequal in view of Laboreau so that the device can be better fit and be secured to, differing

sizes and shapes of bone so that adequate support can be provided for recovery.

7. I respectfully disagree for the following reasons.

First, the implant of Laboreau is a staple. It is not in two planes, and it is an implant in which the mechanics of the implant are to prevent the two legs from separating in order to hold the fracture site closed. In this regard, the legs and the metal bridge between them have to be of sufficient strength to prevent the legs from being spread apart. The offset nature of the bridge is to conform to the surface contour of the bone from one fragment to another. In contrast, the offset buttress pin in the application is loaded axially (or longitudinally) so that the line of force is in line with the long axis of the U-shaped member. There is essentially no force that causes the legs to diverge. The implant does not need to be bulky and strong to resist opening up, which is important for the site of application at the wrist where the bulk of a strong implant will lead to tendon irritation and rupture.

Furthermore, the offset in the buttress pin of the application is in the length of the legs (in order to contour to the geometry of the joint surface) or in the width of the U-shaped portion of the implant (in order to match the width of the bone as you go from proximal to distal. The first length change is at 90 degrees to the U-shaped portion of the implant and would have nothing to do with the device of Laboreau. The second issue (changing the width of the U-shaped portion) has to do with the fit of the U-shaped portion as it courses longitudinally along the bone. Since the implant of Laboreau has the U-shaped portion at 90 degrees to the long axis of the bone, the change in width is for a totally different purpose. Moreover, the change in width is in a totally different plane than the application of the external load; therefore I think this is not an obvious inventive step.

As far as the hairpin of Gasper is concerned, I am at a loss how he can see any similarity of function. The double bends in the hat pin are not at different lengths or positions so would appear to have no influence on a patent based on the offset nature of the wire form.

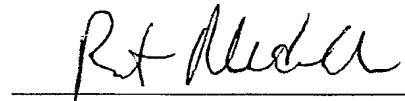
Finally, I can state that I have used the wire forms referenced in Patent No. 5,709,682 longer than anyone in the world, and it took me years before I recognized the issue that

required an offset buttress pin as a solution. I have been fully aware of the type of staple shown, and I think as the world expert on wire forms I can unequivocally state that this is not 'obvious to one skilled in the art'.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date:

8-10-10

A handwritten signature in black ink, appearing to read "Rt Medoff", written over a horizontal line.

Robert J. Medoff

## EXHIBIT I

Brief Curriculum Vitae  
Robert J. Medoff, M.D.  
Oct 2008

Name: Robert J. Medoff, M.D.

Home Address: 159 Ku'ukama Street  
Kailua, Hawaii 96734  
808-262-8752

Business Address: 30 Aulike Street, Suite 506  
Kailua, Hawaii 96734  
808-261-4658

46-001 Kamehameha Hwy, Suite 402  
Kaneohe, Hawaii 96744  
808-235-6474

Birthdate: 1954

Birthplace: Philadelphia, Pennsylvania

Education:  
Undergraduate: University of Pennsylvania  
Philadelphia, Pennsylvania  
B.A. / Physics, 1976  
September 1972

Varsity Letter / Sailing, 1975

Medical School: University of Pennsylvania  
Philadelphia, Pennsylvania  
M.D., 1979

Residencies: General Surgery  
University of Hawaii Integrated Surgical Residency  
Honolulu, Hawaii  
June 1979 - June 1981

Orthopaedic Surgery  
Campbell Clinic  
869 Madison Avenue  
Memphis, Tennessee 38104  
January 1982 - December 1984

Hospital appts, present:

Shriner's Hospital for Crippled Children, Honolulu Unit  
Courtesy staff  
1310 Punahou Street  
Honolulu, Hawaii 96826  
April 1986 - present

The Queen's Medical Center  
Consulting staff  
1301 Punchbowl Street  
Honolulu, Hawaii 96813  
July 1986 - present

Tripler Army Medical Center  
Consulting staff  
Honolulu, Hawaii  
August 1988 - present

Castle Medical Center  
Active staff  
Kailua, Hawaii  
September 1989 - present

Current academic appt:

John A Burns Scholl of Medicine  
University of Hawaii  
Assistant Clinical Professor of Orthopaedic Surgery  
Honolulu, Hawaii  
1986 – present

Publications:

Medoff R. Use Of Standard X-rays And Classification Systems In Guiding Treatment. In Fractures and Injuries of the Distal Radius and Carpus. Ed David Slutsky and Lee Osterman, Elsevier, in print 2009.

Medoff R. Distal Radius Fractures: Classification and Management . in Rehabilitation of the Hand and Upper Extremity, 6th Edition. ed Osterman, et al., in print.

Medoff R. : Fragment-Specific Fixation of Distal Radius Fractures. In Operative Techniques in Orthopaedic Surgery, ed Thomas Hunt, Lippincott, in print.

Medoff, R. (May 2008). The Fractured Wrist (DVD-ROM) Virtual Fellowship Interactive Multimedia Program. American Academy of Orthopaedic Surgeons. Steinman S, Ring D, Ladd A ed.

Medoff R. Fragment-Specific Fixation of Distal Radius Fractures Atlas of the Hand Clinics: 11(2), 163-174, Sep 2006.

Medoff, R. (2006). Fragment Specific Fixation of Distal Radius. Wrist and Elbow Reconstruction & Arthroscopy; A Master Skills Publication. T. Trumble and J. Budoff. Rosemont, American Society for Surgery of the Hand: 183-192.

Medoff, R. (2006). Plating of Distal Radius Fractures. Wrist and Elbow Reconstruction & Arthroscopy; A Master Skills Publication.

T. Trumble and J. Budoff. Rosemont, American Society for Surgery of the Hand: 163-182.

Benson, L., Medoff, R. (2006). Fragment Specific Fixation of Distal Radius Fractures. Injuries to the Distal Radius and Carpus. D. Slutsky and L. Osterman. Elsevier: (in print)

Medoff, R. (2006). Radiographic Evaluation and Classification of Distal Radius Fractures. Injuries to the Distal Radius and Carpus. D. Slutsky and L. Osterman. Elsevier: (in print)

Medoff, R. (2007). Fragment Specific Fixation of Distal Radius Fractures. Operative Techniques in Hand Surgery. T. Hunt. Lippincott, Williams, and Wilkins: (in print)

Chapter: Fragment Specific Fixation  
In: Atlas of Hand Clinics  
Elsevier (in print)

Essential Radiographic Evaluation for Distal Radius Fractures  
Hand Clinics, 2005 21(3), 279-288

Open Reduction and Immediate Motion of Intra-articular Distal Radius Fractures With a Fragment-Specific Fixation System, Medoff, RJ, Kopylov, P. Arch Am Acad Orthop Surg 1999; 2; 53-61

Medoff RJ, Kopylov P. Immediate internal fixation and motion of comminuted distal radius fractures using a new fragment specific fixation system. Orthopaedic Transactions 1998-1999; 22(1): 165.

Marumoto JM, Mitsunaga MM, Richardson AB, Medoff RJ, Mayfield GW.  
Late patellar tendon ruptures after removal of the central third for anterior cruciate ligament reconstruction. A report of two cases. Am J Sports Med. 1996 Sep-Oct;24(5):698-701.

Axial Compression Screw  
in Campbell's Operative Orthopaedics  
Eighth Edition  
pgs 900-901, pgs 907-909

section on Allograft Ligament Reconstruction  
in Campbell's Operative Orthopaedics  
Seventh Edition

Medoff, R.J., Maes, K.: Axial Compression Screw, A New Implant for Unstable Trochanteric Fractures of the Hip, JBJS, Sep 91

Albertson KS, Medoff RJ, Mitsunaga MM.  
The use of periosteally vascularized autografts to augment the fixation of large segmental allografts. Clin Orthop Relat Res. 1991 Aug;(269):113-9.

Medoff, R.J.: Injuries to the Hip in Athletes.  
Annals of Sports Medicine, 3(2): 73-76, 1987

Medoff, R.J.: Soft Tissue Healing  
Annals of Sports Medicine, 3(2): 67-70, 1987

Medoff, R.J.: Insertion of Distal Screws in  
Interlocking Nail Fixation of Femoral Fractures  
J Bone J Surg, 68A: 1275-1277, Oct 1986

Medoff, R.J.; Medskar, L.R.; Headley, S.L.;  
Fortune, H.T.: Additional 1+ States in 20F  
Physical Review, 14: 1-3, July 1976  
(Supported by grant from National Science Foundation)

Ginsberg, M.D., Medoff, R.J., and Reivich, M.:  
Heterogeneities of Regional Cerebral Blood Flow in  
Hypoxic-Ischemic Rats  
Stroke, 7(2): 132-134, March-April 1976

Course director:

The Wrist Injury Course: from Trauma to Rehabilitation.  
Sponsored by Univ of Hawaii, Sheraton Maui Resort  
Oct 31 – Nov 2, 2008.

Treatment of Wrist Injuries, Advanced Surgical Techniques  
Sponsored by Univ of Hawaii  
Haleiwa, Hawaii  
Oct 15-17, 2005

Current Options in the Treatment of Wrist Fractures  
AAOS Orthopaedic Learning Center, Rosemont, IL  
May 14-15, 2004

Advanced Surgical Treatment of Injuries of the Wrist  
Sponsored by Univ of Hawaii  
Kauai, Hawaii  
Nov 7-9, 2003

Current Options in the Treatment of Distal Radius Fractures  
Berger, R, Medoff, RJ  
AAOS Orthopaedic Learning Center  
Sep 20-21, 2002

Advanced treatment of Wrist Injuries  
Medoff, RJ, Ladd, A  
Grand Cayman Island Nov 30-Dec 2 2001  
CME accredited 17.5 hrs

Wrist injury treatment for the 21<sup>st</sup> century  
Medoff, RJ, Ladd, A  
Grand Cayman Island, Nov 3-5 2000  
CME accredited 17.5 hrs



Treatment of Distal Radius Fractures, Advanced Surgical  
Techniques Course  
Medoff, RJ, Ladd, A Course directors  
Maui, Hawaii, May 1999

Hawaii Orthopaedic Association Annual Spring Symposium  
Meeting Chairman  
May 1993

Previous Job Experience: Computer Programmer  
Cerebrovascular Research Laboratory  
University of Pennsylvania  
Philadelphia, Pennsylvania  
1971-1979

Prior clinical/professional practice:

Straub Clinic and Hospital, Inc.  
888 South King Street  
Honolulu, Hawaii 96813  
(808)522-4000  
January 1986 - May 1990

The Campbell Clinic  
869 Madison Avenue  
Memphis, Tennessee 38104  
Clinical Instructor/Orthopaedic Staff/Attending Trauma Staff  
January 1985 - January 1986

Elvis Presley Regional Trauma Center  
Attending Staff  
Memphis, Tennessee  
Attending Staff January 1985 - January 1986

Previous Team Physician: Rhodes (Southwestern) College  
Team Physician Football Team  
Memphis, Tennessee  
1985

Memphis State University  
Assistant Team Physician  
Memphis, Tennessee  
1985

Old Number Seven Rugby Team  
Team Physician  
Memphis, Tennessee  
1985

ILH Football League (7 schools)  
Team Physician  
Honolulu, Hawaii  
1986 - 1990

Consulting physician

University of Hawaii Department of Athletics  
Honolulu, Hawaii  
1986 - 1990

Team physician  
Rainbow Classic National Intercollegiate  
Basketball Conference  
Honolulu, Hawaii  
December 1987

Academic Appointments:  
Prior:

University of Tennessee Center for the Health Sciences  
Memphis, Tennessee  
Clinical instructor in Orthopaedic Surgery  
1985

Director and Founder Soft Tissue Allograft Bank  
University of Tennessee/Campbell Clinic/University of  
Tennessee  
Memphis, Tennessee  
1985

Founder and Director Hawaii Allograft Bank  
Honolulu, Hawaii  
1986 - 1990

Tripler Army Medical Center Orthopaedic Residency  
Teaching Staff  
Honolulu, Hawaii  
1988 - present

Shriner's Hospital Teaching Staff  
Honolulu, Hawaii  
1986 - present

Research Experience:

Recipient of Resident Research Fellowship by  
Orthopaedic Research and Education Foundation, 1984  
Research in ligament and soft tissue healing with  
electromagnetic fields

Clinical research in allograft use for anterior  
cruciate repair

Axial compression screw, design and biomechanical  
testing starting in 1984;  
clinical testing started in 1988

Hawaiian Supracondylar Device  
Design, biomechanical testing from 1989

TriMed Wrist Fixation System  
Design and development, 1994 - present

## Patents (issued and pending):

Axial Compression Screw (USA 4628923)  
Implantable Surgical buttressing device (USA 5941878)  
Asymmetric screw hole angles (USA 6077266)  
Pin Plate (USA 5931839)  
Locking pin plate (USA 7044951)  
Small Fragment Clamp (USA 5709682, Sweden 506462)  
L-Plate (USA 5718704, Sweden 505453)  
Graft Constraint Devices (USA 6113603)  
Sleds (USA 7037708)  
Bearing plate (USA appl 20050154392)  
Assymetrical buttress pins/post washer (USA appl 20050010228)  
Bullet fixation device (USA appl 20050070902)  
Sidewinder plate (USA appl not yet assigned)  
Trigger knife (USA appl not yet assigned)

(Additional international patents and patents pending)

## Societies:

## Active:

Hawaii Orthopaedic Association  
(President 1993)

Fellow, American Academy of Orthopaedic Surgeons

## Miscellaneous:

Honorary Ambassador to Guam  
Awarded for crippled children's care  
July, 1989

## Miscellaneous:

Crippled Childrens field clinics for Shriner's Hospital

Kosrae, Truk, Pohnpei (Federated States of Micronesia)  
October, 1995

Saipan, Guam, Palau  
June, 1992

Tonga, American Samoa, Western Samoa  
May, 1991

Kosrae, Truk, Pohnpei  
May, 1990

Saipan, Guam, Palau  
July, 1989

Tonga, American Samoa, Western Samoa  
July, 1988

## Recreation:

Surfing

## EXHIBIT II

PAT. NO.	Title
1 7,749,257	<b>T</b> <u>Bearing plate for use in fracture fixation having a spherical bearing hole with yielding expandability</u>
2 7,267,678	<b>T</b> <u>Intramedullary implant for fracture fixation</u>
3 7,195,633	<b>T</b> <u>Fracture fixation system</u>
4 7,044,951	<b>T</b> <u>Fracture fixation device in which a fixation pin is axially restrained</u>
5 7,037,308	<b>T</b> <u>Implant device for applying compression across a fracture site</u>
6 6,113,603	<b>T</b> <u>Graft constraint device</u>
7 6,077,266	<b>T</b> <u>Method of enabling bone screws to be installed at an angle in underlying bone</u>
8 5,941,878	<b>T</b> <u>Implantable, surgical buttressing device</u>
9 5,931,839	<b>T</b> <u>Pin plate for fixation of bone fractures</u>
10 5,718,704	<b>T</b> <u>L-shape surgical buttress plate</u>
11 5,709,682	<b>T</b> <u>Surgical clamp for fixation of bone fragments</u>
12 4,628,923	<b>T</b> <u>Axial compression device</u>